

REMARKS**I. Status of Claims**

Upon entry of these amendments, claims 1, 5-11, 36-39, 41-47, and 49 are pending. Claims 5, 36, 39, and 49 have been amended. Claims 40 and 48 have been canceled. The Office has indicated that claims 1 and 6-11 are allowed.

In the interests of expediting prosecution, claims 5, 36, 39, and 49 have been amended. Applicants respectfully submit that no new matter has been introduced with these amendments and therefore request entry of the amendments.

Cancellation of the claims is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications hereof containing the subject matter of the canceled claims.

II. Withdrawn Rejections

Applicants thank the Examiner for withdrawing the rejection of claim 47 for failing to comply with the written description requirement for the reasons set forth on page 3, section 6 of the Action mailed August 28, 2007 and for also withdrawing the rejection of claims 5 and 36-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

III. Rejection under 35 U.S.C. § 112, first paragraph, new matter

Claims 47 and 48 under 35 U.S.C. 112, first paragraph have been rejected as failing to comply with the written description requirement and thus constituting new matter. The Office acknowledges that the fragments listed in claims 47 and 48 are recited in the specification at pages 22 and 23 but asserts that the context of these recitations does not overlap with the claimed invention.

To the extent the rejections apply to the presently pending claims, Applicants respectfully traverse this rejection and its supporting remarks. Written description merely requires
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that the specification as filed allow a person of ordinary skill to recognize that Applicants had possession of the invention. The support in the specification can be *in haec verba*, implicit, or inherent. MPEP § 2161(I)(B).

Pending claim 47 is directed to an isolated nucleic acid molecule of any one of claims 5, 36, or 39, wherein the nucleic acid molecule comprises a specific nucleotide fragment of SEQ ID NO: 1. As acknowledged by the Office, there is explicit support for the specific nucleotide fragment recited in claim 47 in the specification at page 22 (paragraph 81 of the published application). Applicants respectfully submit that the cited section also provides implicit support for the presently claimed invention. The pertinent portion of paragraph 81 of the specification of US2002/0004239 states: “Marker protein-specific probes can be generated using the cDNA sequence disclosed in SEQ ID NO: 1 ... *A preferable region for selecting probes is within nucleotide positions 446-1173 of SEQ ID NO: 1*”. In the paragraph immediately above, the specification describes methods for assaying body samples for the presence of marker protein mRNA using nucleic acid hybridization probes. When read in context of the rest of the specification, the cited section does more than merely provide explicit support for the fragment itself. By disclosing nucleotide positions 446-1173 of SEQ ID NO:1 as a preferred region for selection of nucleic acid hybridization probes useful for detecting the identified polynucleotide, Applicants indicate to those of skill in the art that nucleic acid molecules lacking variation in this region and therefore comprising nucleotides 446-1173 of SEQ ID NO: 1 are a contemplated embodiment.

Further support for nucleic acid molecules comprising the recited nucleotide fragment is found in the sections of the specification describing the characteristics of the novel polynucleotide sequence discovered by Applicants, such as paragraph 32, Example 1, and the Figures. Paragraph 32 describes the first 30 amino acids of the protein as a putative signal peptide. Figure 2 provides the sequence of this signal peptide. Upon reviewing Figure 4 showing the ORF of SEQ ID NO: 1 as spanning nucleotides 359 to 1173 of SEQ ID NO:1, one of skill would readily recognize that the nucleotides which encode the polypeptide encoded by the novel polynucleotide (and not the signal peptide) correspond to nucleotides 446 to 1173 of SEQ ID NO: 1. As such, one of skill would

readily recognize that variant nucleic acids comprising nucleotides 446 to 1173 of the SEQ ID NO: 1 are contemplated by Applicants.

In view of the above, Applicants respectfully submit that the specification as filed provides more than ample support for the presently pending claims. Withdrawal of the new matter rejection is respectfully requested.

IV. Rejection under 35 U.S.C. § 112, first paragraph, written description

The rejection of claims 5 and 36-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been maintained. In particular, the Office takes issue with Applicants' attempts to draw a parallel with Example 14 of the Office's previously issued Synopsis of Application of Written Description Guidelines, asserting that Applicants do not provide information, such a identification of a catalytic domain, and that overexpression in metastatic human breast cancer cells as compared to low or non-metastatic human breast cells is a characteristic and not a function.

To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection and its supporting remarks. Applicants assert that characteristics of the claimed sequences have been provided which would "allow persons of ordinary skill to recognize that [he or she] invented what is claimed." As recognized by the Office, the court in *Regents of the University of California vs. Eli Lilly* noted that an adequate written description of DNA "requires a precise definition, such as by structure, formula, chemical name or physical properties ..." Each of the presently pending claims conforms with the guidance provided by the Federal Circuit. Each of the independent claims 5, 36, and 39 and the dependent claims therefrom provides a sequence of a representative species.

Applicants respectfully draw the Examiner's attention to the new Written Description Training Materials issued since the mailing of the present Office Action which further clarify the Office's position on written description (www.uspto.gov/web/menu/written.pdf). Example 10 provides a claim to an "isolated variant of a protein comprising the amino acid sequence shown in SEQ ID NO: 3, wherein the variant comprises an *amino acid sequence that is at least 95% identical* sf-2511897 v3

to SEQ ID NO: 3.” The Example notes that the claimed 95% identical variants can have amino acid substitutions, deletions, insertions, or additions as compared to SEQ ID NO: 3 but that those skilled in the art would expect members of the genus to have properties similar to those of SEQ ID NO: 3 because of the high degree of structural similarity. The Example then concludes that in view of the disclosure of the sequences, one of skill would easily be able to routinely recognize, make, and identify variants having 95% identity to SEQ ID NO: 3 and as such, there is sufficient written description for claim 2.

Similar to the claims described in Example 10, the presently pending claims recite nucleic acids having a specific structure without specifying any function, such as expression at a higher level in metastatic cells relative to non-metastatic cells. In particular, independent claim 5 and all claims dependent therefrom are directed to an isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide having specified amino acid sequences with *up to 5 conservative substitutions* and independent claim 36 and 39 and all claims dependent therefrom are directed to an isolated nucleic acid molecule comprising a polynucleotide *at least 95% identical* to polynucleotide encoding specified amino acids. The characteristic of having 95% identity to a polynucleotide encoding specified amino acid sequences or up to 5 conservative substitutions of specified amino acid sequences confers a high degree of structural similarity at least commensurate with that described in Example 10.

In view of the above, Applicants submit that the presently pending claims are fully supported by the specification as filed. Withdrawal of the rejection is respectfully requested.

V. Rejection under 35 U.S.C. § 112, second paragraph, indefiniteness

Claims 47-49 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the Office asserts that claims 47 and 48 are indefinite because it is clear and acknowledged by Applicants that the fragments do not encode the recited amino acids but the

dependency of the claims on claims 5, 36, and 39 suggests that they do encode the recited amino acids.

To the extent the rejections apply to the pending claims, Applicants respectfully traverse the rejection and its supporting remarks. The dependency of claim 47 on claims 5 and 36, and 39 is merely intended to increase the compactness of the claim set and is not intended to suggest that the specified nucleotide fragment (446 to 1173 of SEQ ID NO: 1) encodes the recited amino acids. By way of example, if claim 47 were rewritten to incorporate the limitations of currently pending claim 5, it would read as follows: An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide wherein, except for no more than 5 conservative amino acid substitutions, said polypeptide has an amino acid sequence selected from the group consisting of: (a) amino acids 1 to 273 of SEQ ID NO:2; (b) amino acids 2 to 273 of SEQ ID NO:2; and (c) amino acids 26 to 273 of SEQ ID NO:2, said nucleic acid molecule comprising nucleotides 446 to 1173 of SEQ ID NO: 1. As made clear by rewriting the claim in independent form, all that claim 47 does is to limit the genus of nucleic acid molecules of claims 5, 36, and 39 to those comprising nucleotides 446 of 1173 of SEQ ID NO: 1. As such, claim 47 merely specifies the nucleotide sequence of a portion of a nucleic acid encoding certain amino acid sequences. It does not imply that the specified nucleotide sequence (446 to 1173 of SEQ ID NO: 1) encodes a particular amino acid sequence. Accordingly, Applicants have maintained claim 47 as submitted in the last response.

The Office also asserts that claim 49 is indefinite because it implies that conservative amino acid substitutions are made within the isolated nucleic acid molecule. Applicants respectfully traverse the rejection and its supporting remarks. However, in the interests of expediting prosecution, Applicants have amended the claim to clarify the language.

Withdrawal of the rejections for indefiniteness is respectfully requested.

VI. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is

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determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

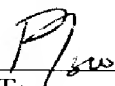
In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. **223002105400**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

In addition, please direct all further communications in this application to:

Lisa Alexander
Novartis Vaccines and Diagnostics, Inc.
Intellectual Property Department X-168
P.O. Box 8097
Emeryville, CA 94662-8097
Tel: (510) 923-3004
Fax: (510) 655-3542

Dated: June 23, 2008

Respectfully submitted,

By 
Patricia Tsao
Registration No.: 50,713

MORRISON & FOERSTER LLP
425 Market Street
San Francisco, California 94105-2482
(415) 268-6642